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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

ROBERT PEERY,

Plaintiff,

Case No. CV-15-1883-PHX-DGC

v.

C. R. BARD, INC., a foreign corporation;
AND BARD PERIPHERAL VASCULAR
INC., an Arizona Corporation, and DOES 1
through 100 inclusive,

Defendants.

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND DEFENSES TO
PLAINTIFF'S COMPLAINT AND
DEMAND FOR TRIAL BY JURY**

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV")
(collectively "Defendants"), through undersigned counsel, hereby file their answer and
defenses to Plaintiff's Complaint (the "Complaint") as follows:

THE PARTIES

1
2 1. To the extent the allegations in Paragraph 1 of the Complaint purport to cast
3 liability upon Defendants, either directly or indirectly, those allegations are denied.
4 Defendants are without information sufficient to form a belief as to the truth of the remaining
5 allegations contained in Paragraph 1 of the Complaint and, on that basis, deny them.

6 2. Defendants admit that Bard is a New Jersey Corporation and that Bard is
7 authorized to do business, and does business, in the State of Tennessee. Defendants admit
8 that Bard owns a facility where vena cava filters are manufactured. Bard denies any
9 remaining allegations contained in Paragraph 2 of the Complaint.

10 3. Defendants admit that BPV is an Arizona Corporation and that BPV is
11 authorized to do business, and does business, in the State of Tennessee. Defendants further
12 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
13 has designed, sold, marketed, and distributed filters under the trademarks Recovery® and
14 G2® Filter Systems. Defendants further admit that BPV is a wholly owned subsidiary of
15 Bard. Defendants deny any remaining allegations contained in Paragraph 3 of the Complaint.

16 4. Paragraph 4 of the Complaint does not include any factual allegations and, as a
17 result, requires no response by Defendants. However, to the extent Paragraph 4 purports to
18 cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

19 5. The allegations of Paragraph 5 of the Complaint are not directed to Bard or
20 BPV, and, as a result, require no response by Defendants. However, to the extent
21 Paragraph 5 purports to cast liability either directly or indirectly upon Defendants, said
22 Paragraph is expressly denied.

23 6. The allegations of Paragraph 6 of the Complaint are not directed to Bard or
24 BPV, and, as a result, require no response by Defendants. However, to the extent
25 Paragraph 6 purports to cast liability either directly or indirectly upon Defendants, said
26 Paragraph is expressly denied.

JURISDICTION AND VENUE

7. Defendants do not contest that the injuries and damages alleged within The Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever.

8. Defendants do not contest that the injuries and damages alleged within The Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Western District of Tennessee.

9. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Western District of Tennessee.

ALLEGATIONS

10. Defendants deny the allegations contained in Paragraph 10 of the Complaint.

11. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® Filter Systems. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 11 of the Complaint.

12. Defendants deny the allegations contained in Paragraph 12 of the Complaint, including all sub-parts thereof.

1 13. Defendants lack knowledge or information sufficient to form a belief as to the
2 truth of the allegation regarding the time frame when inferior vena cava filters were first
3 introduced on the market or the identity of manufacturers of inferior vena cava filters.
4 Defendants deny any remaining allegations of Paragraph 13 of the Complaint.

5 14. Defendants admit that inferior vena cava filters are intended to prevent injury or
6 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
7 that inferior vena cava filters may be designed for permanent placement, temporary
8 placement, or both. Defendants deny any remaining allegations of Paragraph 14 of the
9 Complaint.

10 15. Defendants admit that the inferior vena cava is a large vein that receives blood
11 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
12 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
13 human health, including sometimes death. Defendants deny any remaining allegations of
14 Paragraph 15 of the Complaint.

15 16. Defendants admit that certain people are at an increased risk for the
16 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
17 to form a belief as to the truth of the allegations as stated regarding the various risk factors
18 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
19 deny them. Defendants deny any remaining allegations of Paragraph 16 of the Complaint.

20 17. Defendants admit that patients at a high risk for developing deep vein
21 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
22 including but not limited to the medications listed in Paragraph 17 of the Complaint.
23 Defendants further admit that inferior vena cava filters may also be used to treat patients who
24 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
25 lack knowledge or information sufficient to form a belief as to the truth of any remaining
26 allegations contained in Paragraph 17 of the Complaint and, on that basis, deny them.

1 18. Defendants lack knowledge or information or information sufficient to form a
2 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
3 were first introduced on the market. Defendants also lack knowledge or information
4 sufficient to form a belief as to the truth of the allegation regarding the time frame when
5 optional or retrievable filters came to be marketed or the other allegations regarding optional
6 or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®,
7 G2®, and Eclipse™ Filters were cleared by the FDA for optional use as retrievable inferior
8 vena cava filters. Defendants deny any remaining allegations contained in Paragraph 18 of
9 the Complaint.

10 19. Defendants admit that the Recovery® Filter was cleared by the FDA for
11 permanent placement on November 27, 2002, pursuant to an application submitted under
12 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. The allegations pertaining to
13 the requirements of Section 510(k) contained in Footnote 1 are legal conclusions of law to
14 which no answer is required. Defendants deny any remaining allegations contained in
15 Paragraph 19 of the Complaint, including any allegations contained in Footnote 1.

16 20. Defendants admit that the Recovery® Filter was cleared by the FDA for
17 retrievable placement on July 25, 2003, pursuant to an application submitted under
18 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. Defendants deny any remaining
19 allegations contained in Paragraph 20 of the Complaint.

20 21. Defendants deny the allegations contained in Paragraph 21 of the Complaint.

21 22. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
22 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
23 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
24 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
25 allegations contained in Paragraph 22 of the Complaint.

26 23. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
27 manufacture of the Recovery Filter and further admits that Nitinol contains shape memory.
28

1 However, to the extent Paragraph 23 purports to cast liability either directly or indirectly
2 upon Defendants, said Paragraph is expressly denied.

3 24. Defendants admit that the Recovery® Filter was designed to be inserted
4 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
5 delivered via an introducer sheath, which is included in the delivery system for the device.
6 Defendants are without knowledge or information sufficient to form a belief as to the truth of
7 the allegations contained in Paragraph 24 of the Complaint regarding the typical practices of
8 physicians, including physician methods for determining successful implantation of the
9 Recovery® Filter and, on that basis, such allegations are denied. Defendants deny any
10 remaining allegations of Paragraph 24 of the Complaint.

11 25. Defendants deny the allegations contained in Paragraph 25 of the Complaint,
12 including any allegations contained in Footnote 2.

13 26. Defendants deny the allegations contained in Paragraph 26 of the Complaint.

14 27. Defendants deny the allegations contained in Paragraph 27 of the Complaint.

15 28. Defendants admit that there are various well-documented complications that
16 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
17 Defendants further admit that it is well documented that many instances of filter fracture
18 and/or migration result in no complications whatsoever but, rather, are completely
19 asymptomatic. By way of further response, Bard states that there are incidents related to the
20 occurrence of known complications associated with every manufacturer of inferior vena cava
21 filters. Defendants deny the remaining allegations of Paragraph 28 of the Complaint,
22 including all sub-parts thereof.

23 29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.

24 30. Defendants deny the allegations contained in Paragraph 30 of the Complaint.

25 31. Defendants deny the allegations contained in Paragraph 31 of the Complaint.

26 32. Defendants admit that there are various well-documented complications that
27 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
28

1 Defendants further admit that it is well documented that many instances of filter fracture
2 and/or migration result in no complications whatsoever but, rather, are completely
3 asymptomatic. By way of further response, Bard states that there are incidents related to the
4 occurrence of known complications associated with every manufacturer of inferior vena cava
5 filters. Defendants deny the remaining allegations of Paragraph 32 of the Complaint,
6 including all sub-parts thereof.

7 33. Defendants deny the allegations contained in Paragraph 33 of the Complaint.

8 34. Defendants deny the allegations contained in Paragraph 34 of the Complaint.

9 35. Defendants admit that, as part of their continuing efforts to constantly evaluate
10 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
11 continually striving to improve the life-saving performance of those devices. The G2® Filter
12 was developed in furtherance of those efforts. Defendants deny the remaining allegations
13 contained in Paragraph 35 of the Complaint.

14 36. Defendants admit the G2® Filter System was cleared by the United States Food
15 and Drug Administration pursuant to an application submitted under Section 510(k) of the
16 Food, Drug and Cosmetic Act in 2005. Defendants admit that the G2® Filter was originally
17 cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was
18 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter.
19 Defendants deny any remaining allegations contained in Paragraph 36 of the Complaint.

20 37. Defendants admit that, as part of their continuing efforts to constantly evaluate
21 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
22 continually striving to improve the life-saving performance of those devices. The G2® Filter
23 was developed in furtherance of those efforts. Defendants deny any remaining allegations of
24 Paragraph 37 of the Complaint.

25 38. Defendants deny the allegations contained in Paragraph 38 of the Complaint.

26 39. Defendants deny the allegations contained in Paragraph 39 of the Complaint.

1 40. Defendants admit that there are various well-documented complications that
2 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
3 Defendants further admit that it is well documented that many instances of filter fracture
4 and/or migration result in no complications whatsoever but, rather, are completely
5 asymptomatic. By way of further response, Bard states that there are incidents related to the
6 occurrence of known complications associated with every manufacturer of inferior vena cava
7 filters. Defendants deny the remaining allegations of Paragraph 40 of the Complaint,
8 including all sub-parts thereof.

9 41. Defendants admit that there are various well-documented complications that
10 may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard
11 states that there are incidents related to the occurrence of known complications associated
12 with every manufacturer of inferior vena cava filters. By way of further response, Bard states
13 that information available in the public domain, including the FDA MAUDE database, is not
14 a comprehensive analysis of all instances of such complications. Defendants deny the
15 remaining allegations of Paragraph 41 of the Complaint.

16 42. Defendants admit that there are various well-documented complications that
17 may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard
18 states that there are incidents related to the occurrence of known complications associated
19 with every manufacturer of inferior vena cava filters. By way of further response, Bard states
20 that information available in the public domain, including the FDA MAUDE database, is not
21 a comprehensive analysis of all instances of such complications. Defendants deny the
22 remaining allegations of Paragraph 42 of the Complaint.

23 43. Defendants deny the allegations contained in Paragraph 43 of the Complaint.

24 44. Defendants deny the allegations contained in Paragraph 44 of the Complaint.

25 45. Defendants deny the allegations contained in Paragraph 45 of the Complaint.

26 46. Defendants deny the allegations contained in Paragraph 46 of the Complaint,
27 including all sub-parts thereof.
28

47. Defendants deny the allegations contained in Paragraph 47 of the Complaint.

48. Defendants deny the allegations contained in Paragraph 48 of the Complaint.

49. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 49 of the Complaint and, on that basis, denies them.

50. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. Defendants deny any remaining allegations of Paragraph 50 of the Complaint.

51. Defendants deny the allegations contained in Paragraph 51 of the Complaint.

52. Defendants deny the allegations contained in Paragraph 52 of the Complaint.

53. Defendants deny the allegations contained in Paragraph 53 of the Complaint.

54. Defendants deny the allegations contained in Paragraph 54 of the Complaint.

55. The allegations contained in Paragraph 55 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 55 of the Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of the Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of the Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of the Complaint.

59. Defendants deny the allegations contained in Paragraph 59 of the Complaint.

FIRST CAUSE OF ACTION

(Negligence)

60. Defendants incorporate by reference their responses to Paragraphs 1-59 of the Complaint as if fully set forth herein.

61. Defendants deny the allegations of Paragraph 61 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters

are manufactured and that filters under the trademarks Recovery® and G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 61 of the Complaint.

62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. Defendants deny any remaining allegations of Paragraph 62 of the Complaint.

63. The allegations contained in Paragraph 63 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 63 of the Complaint.

64. Defendants deny the allegations contained in Paragraph 64 of the Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of the Complaint, including all sub-parts thereof.

66. Defendants deny the allegations contained in Paragraph 66 of the Complaint.

67. Defendants deny the allegations contained in Paragraph 67 of the Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of the Complaint, including all sub-parts thereof.

69. Defendants deny the allegations contained in Paragraph 69 of the Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of the Complaint.

SECOND CAUSE OF ACTION

(Strict Products Liability – Failure to Warn)

71. Defendants incorporate by reference their responses to Paragraphs 1-70 of the Complaint as if fully set forth herein.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 72 of the Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of the Complaint.

74. The allegations contained in Paragraph 74 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 74 of the Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of the Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of the Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of the Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of the Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of the Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of the Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of the Complaint.

THIRD CAUSE OF ACTION

(Strict Products Liability – Design Defects)

82. Defendants incorporate by reference their responses to Paragraphs 1-81 of the Complaint as if fully set forth herein.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter

1 implanted in Plaintiff and, on that basis, denies them. By way of further response,
 2 Defendants admit that Bard owns a facility where vena cava filters are manufactured and that
 3 filters under the trademark G2® Filter Systems were manufactured at that facility.
 4 Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava
 5 filters and that BPV designed, sold, marketed, and distributed filters under the trademarks
 6 G2® Filter Systems . Defendants deny any remaining allegations contained in Paragraph 83
 7 of the Complaint.

8 84. Defendants deny the allegations contained in Paragraph 84 of the Complaint.

9 85. Defendants deny the allegations contained in Paragraph 85 of the Complaint.

10 86. Defendants deny the allegations contained in Paragraph 86 of the Complaint.

11 87. Defendants deny the allegations contained in Paragraph 87 of the Complaint.

12 88. Defendants deny the allegations contained in Paragraph 88 of the Complaint.

13 89. Defendants deny the allegations contained in Paragraph 89 of the Complaint.

14 **FOURTH CAUSE OF ACTION**

15 **(Strict Products Liability – Manufacturing Defect)**

16 90. Defendants incorporate by reference their responses to Paragraphs 1-89 of the
 17 Complaint as if fully set forth herein.

18 91. Defendants are without knowledge or information sufficient to form a belief as
 19 to the truth of the allegations regarding the trade name of any inferior vena cava filter
 20 implanted in Plaintiff and, on that basis, denies them. By way of further response,
 21 Defendants admit that Bard owns a facility where vena cava filters are manufactured and that
 22 filters under the trademark G2® Filter Systems were manufactured at that facility.
 23 Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava
 24 filters and that BPV designed, sold, marketed, and distributed filters under the trademark
 25 G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 91
 26 of the Complaint.

27 92. Defendants deny the allegations contained in Paragraph 92 of the Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of the Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of the Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of the Complaint.

FIFTH CAUSE OF ACTION

(Breach of Implied Warranty of Merchantability)

96. Defendants incorporate by reference their responses to Paragraphs 1-95 of the Complaint as if fully set forth herein.

97. Defendants deny the allegations contained in Paragraph 97 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 97 of the Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of the Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of the Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of the Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of the Complaint, including all sub-parts thereof.

102. Defendants deny the allegations contained in Paragraph 102 of the Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of the Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of the Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of the Complaint.

SIXTH CAUSE OF ACTION

(Negligent Misrepresentation/Consumer Fraud)

106. Defendants incorporate by reference their responses to Paragraphs 1-105 of the Complaint as if fully set forth herein.

1 107. Defendants deny the allegations contained in Paragraph 107 of the Complaint,
2 including all sub-parts thereof.

3 108. Defendants deny the allegations contained in Paragraph 108 of the Complaint.

4 109. Defendants deny the allegations contained in Paragraph 109 of the Complaint.

5 110. Defendants deny the allegations contained in Paragraph 110 of the Complaint.

6 111. Defendants deny the allegations contained in Paragraph 111 of the Complaint.

7 112. Defendants deny the allegations contained in Paragraph 112 of the Complaint.

8 113. Defendants deny the allegations contained in Paragraph 113 of the Complaint.

9 114. Defendants deny the allegations contained in Paragraph 114 of the Complaint.

10 115. Defendants deny the allegations contained in Paragraph 115 of the Complaint.

11 116. Defendants deny the allegations contained in Paragraph 116 of the Complaint.

12 **PUNITIVE DAMAGES**

13 117. Defendants incorporate by reference their responses to Paragraphs 1-116 of the
14 Complaint as if fully set forth herein.

15 118. Defendants deny the allegations contained in Paragraph 118 of the Complaint.

16 119. Defendants deny the allegations contained in Paragraph 119 of the Complaint,
17 including all sub-parts thereof.

18 120. Defendants deny the allegations contained in Paragraph 120 of the Complaint.

19 121. Defendants deny the allegations contained in Paragraph 121 of the Complaint.

20 **PRAYER FOR DAMAGES**

21 Furthermore, responding to the unnumbered Paragraph, including sub-parts, following
22 the heading "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny
23 the allegations contained in such Paragraph and sub-parts.

24 Further, responding to the prayer for relief as to the first cause of action for negligence
25 against Defendants Bard, BPV and Does 1 through 100, including sub-parts numbered 1
26 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts.
27 Defendants deny that Plaintiff is entitled to any relief requested in the Complaint.
28

1 Further, responding to the prayer for relief as to the second cause of action for strict
2 liability – failure to warn against Defendants Bard, BPV and Does 1 through 100, including
3 sub-parts numbered 1 through 6, Defendants deny the allegations contained in such
4 Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in
5 the Complaint.

6 Further, responding to the prayer for relief as to the third cause of action for strict
7 liability – design defect against Defendants Bard, BPV and Does 1 through 100, including
8 sub-parts numbered 1 through 6, Defendants deny the allegations contained in such
9 Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in
10 the Complaint.

11 Further, responding to the prayer for relief as to the fourth cause of action for strict
12 liability – manufacturing defect against Defendants Bard, BPV and Does 1 through 100,
13 including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such
14 Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in
15 the Complaint.

16 Further, responding to the prayer for relief as to the fifth cause of action for breach of
17 implied warranty against Defendants Bard, BPV and Does 1 through 100, including sub-parts
18 numbered 1 through 5, Defendants deny the allegations contained in such Paragraph and sub-
19 parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint.

20 Further, responding to the prayer for relief as to the sixth cause of action for negligent
21 misrepresentation against Defendants Bard, BPV and Does 1 through 100, including sub-
22 parts numbered 1 through 4, Defendants deny the allegations contained in such Paragraph and
23 sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint.

24 Defendants further deny each and every allegation not specifically admitted herein.

25 **DEFENSES**

26 Defendants allege as affirmative defenses the following:
27
28

1 1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which
2 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

3 2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the
4 negligence of a person or persons or entity for whose acts or omissions Defendants were and
5 are in no way liable.

6 3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of
7 limitations and/or statute of repose.

8 4. If Plaintiff has been damaged, which Defendants deny, any recovery by
9 Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or
10 failed to mitigate their alleged damages. To the extent Plaintiff has failed to mitigate her
11 alleged damages, any recovery shall not include alleged damages that could have been
12 avoided by reasonable care and diligence.

13 5. If Plaintiff has been damaged, which Defendants deny, such damages were
14 caused by the negligence or fault of Plaintiff.

15 6. If Plaintiff has been damaged, which Defendants deny, such damages were
16 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
17 not legally responsible.

18 7. The conduct of Defendants and the subject product at all times conformed with
19 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
20 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
21 part, under the doctrine of federal preemption, and granting the relief requested would
22 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
23 violation of the Supremacy Clause of the United States Constitution.

24 8. If Plaintiff has been damaged, which Defendants deny, such damages were
25 caused by unforeseeable, independent, intervening, and/or superseding events for which
26 Defendants are not legally responsible.

1 9. There was no defect in the product at issue with the result that Plaintiff is not
2 entitled to recover against Defendants in this cause.

3 10. If there were any defect in the products – and Defendants deny that there were
4 any defects – nevertheless, there was no causal connection between any alleged defect and
5 the product on the one hand and any damage to Plaintiff on the other with the result that
6 Plaintiff is not entitled to recover against Defendants in this cause.

7 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
8 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
9 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
10 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
11 either in whole or in part, from all persons or entities whose negligence or fault proximately
12 caused or contributed to cause Plaintiff's alleged damages.

13 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
14 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a
15 manner not intended by Defendants and over which Defendants had no control.

16 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
17 Complaint were caused by a substantial change in the product after leaving the possession,
18 custody, and control of Defendants.

19 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
20 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
21 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
22 Defendants.

23 15. Plaintiff's claims for breach of implied warranty must fail because the product
24 was not used for its ordinary purpose.

25 16. Defendants neither had nor breached any alleged duty to warn with respect to
26 the product, with the result that Plaintiff is not entitled to recover in this cause.

1 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
2 warnings and instructions to learned intermediaries.

3 18. At all relevant times, herein, Plaintiff's physicians were in the position of
4 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
5 benefits of the subject product.

6 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
7 entities for whose conduct Defendants are not legally responsible and the independent
8 knowledge of these persons or entities of the risks inherent in the use of the product and other
9 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
10 damages.

11 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
12 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
13 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
14 unknown, unknowable, or not reasonably foreseeable to Defendants.

15 21. Defendants believe, and upon that ground allege, that Plaintiff were advised of
16 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
17 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
18 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
19 damages that Plaintiff seek to recover herein.

20 22. At all relevant times during which the device at issue was designed, developed,
21 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
22 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
23 information, and instructions, all pursuant to generally recognized prevailing industry
24 standards and state-of-the-art in existence at the time.

25 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
26 result of the alleged conduct and do not have any right, standing, or competency to maintain
27 claims for damages or other relief.
28

1 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
2 estoppel, and/or laches.

3 25. If Plaintiff suffered any damages or injuries, which are denied, Defendants state
4 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
5 doctrines of contributory and/or comparative negligence.

6 26. In the further alternative, and only in the event that it is determined that
7 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
8 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
9 any other defendants, third-party defendants, or other persons, including any party immune
10 because bankruptcy renders them immune from further litigation, as well as any party, co-
11 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

12 27. Should Defendants be held liable to Plaintiff, which liability is specifically
13 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
14 from all collateral sources.

15 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
16 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
17 claims, and the prohibition on double recovery for the same injury.

18 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
19 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
20 over which Defendants had no control.

21 30. The conduct of Defendants and all activities with respect to the subject product
22 have been and are under the supervision of the Federal Food and Drug Administration
23 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
24 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

25 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
26 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
27
28

1 their Answer to file such further pleadings as are necessary to preserve and assert such
2 defenses, claims, credits, offsets, or remedies.

3 32. The device at issue complied with any applicable product safety statute or
4 administrative regulation, and therefore Plaintiff's defective design and warnings-based
5 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
6 comments thereto.

7 33. Plaintiff cannot show that any reasonable alternative design would have
8 rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiff's Complaint to
9 be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could
10 Defendants have known of any alternative design that may be identified by Plaintiff.

11 34. The device at issue was not sold in a defective condition unreasonably
12 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
13 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
14 comparable provisions of the Restatement (Third) of Torts (Products Liability).

15 35. At all relevant times during which the device at issue was designed, developed,
16 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
17 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
18 information, and instructions, all pursuant to generally recognized prevailing industry
19 standards and state-of-the-art in existence at the time.

20 36. Defendants specifically plead all affirmative defenses under the Uniform
21 Commercial Code ("UCC") now existing or which may arise in the future, including those
22 defenses provided by UCC §§ 2-607 and 2-709.

23 37. Plaintiff's alleged damages, if any, should be apportioned among all parties at
24 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
25 Act.

26 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
27 grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiff's Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the Nevada Constitution.

40. Regarding Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the Nevada Constitution, on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

1 (c) the procedures to which punitive damages are awarded fail to provide a
 2 reasonable limit on the amount of the award against Defendants, which thereby
 3 violates the Due Process Clause of the Fourteenth Amendment of the United
 4 States Constitution;

5 (d) the procedures pursuant to which punitive damages are awarded fail to provide
 6 specific standards for the amount of the award of punitive damages which
 7 thereby violates the Due Process Clause of the Fourteenth Amendment of the
 8 United States Constitution;

9 (e) the procedures pursuant to which punitive damages are awarded result in the
 10 imposition of different penalties for the same or similar acts, and thus violate
 11 the Equal Protection Clause of the Fourteenth Amendment of the United States
 12 Constitution;

13 (f) the procedures pursuant to which punitive damages are awarded permit the
 14 imposition of punitive damages in excess of the maximum criminal fine for the
 15 same or similar conduct, which thereby infringes upon the Due Process Clause
 16 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
 17 Fourteenth Amendment of the United States Constitution;

18 (g) the procedures pursuant to which punitive damages are awarded permit the
 19 imposition of excessive fines in violation of the Eighth Amendment of the
 20 United States Constitution;

21 (h) the award of punitive damages to the plaintiff in this action would constitute a
 22 deprivation of property without due process of law; and

23 (i) the procedures pursuant to which punitive damages are awarded permit the
 24 imposition of an excessive fine and penalty.

25 42. Defendants expressly reserve the right to raise as an affirmative defense that
 26 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should
 27 discovery reveal the existence of facts to support such defense.
 28

1 This 27th day of October 2015.

2
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25
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 27, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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